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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, and POZEN INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 3-11-cv-02317 (JAP)(LHG) **ELECTRONICALLY FILED**

ANSWER OF DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC. AND COUNTERCLAIMS TO FIRST AMENDED COMPLAINT

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") by their attorneys, for their answer to the First Amended Complaint by AstraZeneca AB, AstraZeneca LP, and Pozen Inc. (collectively, "AstraZeneca" or "Plaintiffs") respond to allegations as follows:

NATURE OF THE ACTION

1. DRL admits that this action is for patent infringement.

THE PARTIES

2. DRL admits the allegations contained in paragraph 2 of the First Amended First Amended Complaint.

3. DRL admits the allegations contained in paragraph 3 of the First Amended First Amended Complaint.

4. DRL admits the allegations contained in paragraph 4 of the First Amended First Amended Complaint.

5. DRL admits the allegations contained in paragraph 5 of the First Amended First Amended Complaint.

6. DRL admits the allegations contained in paragraph 6 of the First Amended First Amended Complaint.

7. DRL admits the allegations contained in paragraph 7 of the First Amended First Amended Complaint.

8. DRL admits the allegations contained in paragraph 8 of the First Amended First Amended Complaint.

BACKGROUND

The NDA

9. DRL admits the allegations contained in paragraph 9 of the First Amended Complaint.

10. DRL denies the allegations contained in paragraph 10 of the First Amended Complaint.

The Patent-In-Suit

11. DRL denies the allegations of paragraph 11 of the First Amended Complaint, except that DRL admits that the U.S. Patent No. 6,926,907 ("the '907 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," issued on August 9, 2005, and that the First Amended Complaint annexes a copy of the '907 patent as Exhibit A.

12. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 12 of the First Amended Complaint, except that DRL admits that the '907 patent states on its face that the assignee of the patent is Pozen Inc.

13. DRL denies the allegations of paragraph 13 of the First Amended Complaint, except that DRL admits that the U.S. Patent No. 5,714,504 ("the '504 patent"), entitled "Compositions," issued on February 3, 1998, and that the First Amended Complaint annexes a copy of the '504 patent as Exhibit B.

14. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 14 of the First Amended Complaint, except that DRL admits that the '504 patent states on its face that the assignee of the patent is Astra Aktienbolag.

15. DRL denies the allegations of paragraph 15 of the First Amended Complaint, except that DRL admits that the U.S. Patent No. 6,875,872 ("the '872 patent"), entitled "Compounds," issued on April 5, 2005, and that the First Amended Complaint annexes a copy of the '872 patent as Exhibit C.

16. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 16 of the First Amended Complaint, except that DRL admits that the '872 patent states on its face that the assignee of the patent is AstraZeneca.

17. DRL denies the allegations of paragraph 17 of the First Amended Complaint, except that DRL admits that the U.S. Patent No. 7,745,466 ("the '466 patent"), entitled "Form of S-omeprazole," issued on June 29, 2010, and that the First Amended Complaint annexes a copy of the '466 patent as Exhibit D.

18. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 18 of the First Amended Complaint, except that DRL admits that the '466 patent states on its face that the assignee of the patent is AstraZeneca AB.

19. DRL denies the allegations of paragraph 19 of the First Amended Complaint, except that DRL admits that the U.S. Patent No. 7,411,070 ("the '070 patent"), entitled "Form of S-omeprazole," issued on August 12, 2008, and that the First Amended Complaint annexes a copy of the '070 patent as Exhibit E.

20. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 20 of the First Amended Complaint, except that DRL admits that the '070 patent states on its face that the assignee of the patent is AstraZeneca AB.

21. DRL denies the allegations of paragraph 21 of the First Amended Complaint, except that DRL admits that the U.S. Patent No. 6,369,085 ("the '085 patent"), entitled "Form of S-omeprazole," issued on April 9, 2002, and that the First Amended Complaint annexes a copy of the '085 patent as Exhibit F.

22. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 22 of the First Amended Complaint, except that DRL admits that the '085 patent states on its face that the assignee of the patent is AstraZeneca AB.

The ANDA

23. DRL admits the allegations contained in paragraph 23 of the First Amended Complaint.

24. DRL admits the allegations contained in paragraph 24 of the First Amended Complaint.

JURISDICTION AND VENUE

25. DRL admits the allegations contained in paragraph 25 of the First Amended Complaint.

26. DRL admits the allegations contained in paragraph 26 of the First Amended Complaint.

27. DRL admits the allegations contained in paragraph 27 of the First Amended Complaint.

28. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 28 of the First Amended Complaint.

29. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 29 of the First Amended Complaint.

30. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 30 of the First Amended Complaint.

31. DRL admits the allegations in paragraph 31 of the First Amended Complaint.

32. DRL admits the allegations in paragraph 32 of the First Amended Complaint.

33. DRL admits the allegations contained in paragraph 33 of the First Amended Complaint.

34. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 34 of the First Amended Complaint.

35. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 35 of the First Amended Complaint.

36. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 36 of the First Amended Complaint.

37. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 37 of the First Amended Complaint.

38. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 38 of the First Amended Complaint.

39. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 39 of the First Amended Complaint.

40. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 40 of the First Amended Complaint.

COUNT I
(INFRINGEMENT OF THE '907 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

41. DRL incorporates and repeats its responses to paragraphs 1-40 above as if set forth here.

42. DRL admits the allegations contained in paragraph 42 of the First Amended Complaint.

43. DRL admits the allegations contained in paragraph 43 of the First Amended Complaint.

44. DRL admits the allegations contained in paragraph 44 of the First Amended Complaint that DRL's March 11, 2011 Notice Letter "does not address non-infringement of claims 1, 5, 9-17, 21-24, 28-29, 32-35, 37, 41-42, 45-48, and 50-55 of the '907 patent," but denies the balance of the allegations in this paragraph.

45. DRL denies the allegations contained in paragraph 45 of the First Amended Complaint.

46. DRL denies the allegations contained in paragraph 46 of the First Amended Complaint.

47. DRL denies the allegations contained in paragraph 47 of the First Amended Complaint.

48. DRL denies the allegations contained in paragraph 48 of the First Amended Complaint.

49. DRL denies the allegations contained in paragraph 49 of the First Amended Complaint.

COUNT II
(INFRINGEMENT OF THE '504 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

50. DRL incorporates and repeats its responses to paragraphs 1-40 above as if set forth here.

51. DRL admits the allegations contained in paragraph 51 of the First Amended Complaint.

52. DRL admits the allegations contained in paragraph 52 of the First Amended Complaint.

53. DRL admits the allegations contained in paragraph 53 of the First Amended Complaint that DRL's September 19, 2011 Notice Letter "does not address non-infringement of claims 1-3, 5-7, and 10 of the '504 patent," but denies the balance of the allegations in this paragraph.

54. DRL denies the allegations contained in paragraph 54 of the First Amended Complaint.

55. DRL denies the allegations contained in paragraph 55 of the First Amended Complaint.

56. DRL denies the allegations contained in paragraph 56 of the First Amended Complaint.

57. DRL denies the allegations contained in paragraph 57 of the First Amended Complaint.

58. DRL denies the allegations contained in paragraph 58 of the First Amended Complaint.

COUNT III
(INFRINGEMENT OF THE '872 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

59. DRL incorporates and repeats its responses to paragraphs 1-40 above as if set forth here.

60. DRL admits the allegations contained in paragraph 60 of the First Amended Complaint.

61. DRL admits the allegations contained in paragraph 61 of the First Amended Complaint.

62. DRL admits the allegations contained in paragraph 62 of the First Amended Complaint that DRL's September 19, 2011 Notice Letter "does not address non-infringement of claims 1-2, 4-5, 7-8, and 10-11 of the '872 patent," but denies the balance of the allegations in this paragraph.

63. DRL denies the allegations contained in paragraph 63 of the First Amended Complaint.

64. DRL denies the allegations contained in paragraph 64 of the First Amended Complaint.

65. DRL denies the allegations contained in paragraph 65 of the First Amended Complaint.

66. DRL denies the allegations contained in paragraph 66 of the First Amended Complaint.

67. DRL denies the allegations contained in paragraph 67 of the First Amended Complaint.

COUNT IV
(INFRINGEMENT OF THE '466 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

68. DRL incorporates and repeats its responses to paragraphs 1-40 above as if set forth here.

69. DRL denies the allegations contained in paragraph 69 of the First Amended Complaint.

70. DRL denies the allegations contained in paragraph 70 of the First Amended Complaint.

71. DRL denies the allegations contained in paragraph 71 of the First Amended Complaint.

72. DRL denies the allegations contained in paragraph 72 of the First Amended Complaint.

73. DRL denies the allegations contained in paragraph 73 of the First Amended Complaint.

COUNT V
(INFRINGEMENT OF THE '070 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

74. DRL incorporates and repeats its responses to paragraphs 1-40 above as if set forth here.

75. DRL admits the allegations contained in paragraph 75 of the First Amended Complaint.

76. DRL admits the allegations contained in paragraph 76 of the First Amended Complaint.

77. DRL admits the allegations contained in paragraph 77 that DRL's Notice Letter dated September 19, 2011 "does not address invalidity of claims 2 and 4 of the '070 patent," but denies the balance of the allegations in this paragraph of the First Amended Complaint.

78. DRL denies the allegations contained in paragraph 78 of the First Amended Complaint.

79. DRL denies the allegations contained in paragraph 79 of the First Amended Complaint.

80. DRL denies the allegations contained in paragraph 80 of the First Amended Complaint.

81. DRL denies the allegations contained in paragraph 81 of the First Amended Complaint.

82. DRL denies the allegations contained in paragraph 82 of the First Amended Complaint.

COUNT VI
(INFRINGEMENT OF THE '085 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

83. DRL incorporates and repeats its responses to paragraphs 1-40 above as if set forth here.

84. DRL admits the allegations contained in paragraph 84 of the First Amended Complaint.

85. DRL admits the allegations contained in paragraph 85 of the First Amended Complaint.

86. DRL admits the allegations contained in paragraph 86 that DRL's Notice Letter dated September 19, 2011 does not address the invalidity of any claims of the '085 patent, but denies the balance of the allegations in this paragraph of the First Amended Complaint.

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87. DRL denies the allegations contained in paragraph 87 of the First Amended Complaint.

88. DRL denies the allegations contained in paragraph 88 of the First Amended Complaint.

89. DRL denies the allegations contained in paragraph 89 of the First Amended Complaint.

90. DRL denies the allegations contained in paragraph 90 of the First Amended Complaint.

91. DRL denies the allegations contained in paragraph 91 of the First Amended Complaint.

92. DRL denies the allegations contained in paragraph 92 of the First Amended Complaint.

PRAYER FOR RELIEF

93. DRL denies that Plaintiffs are entitled to any of the judgments and relief prayed for in paragraphs A through G of the First Amended Complaint.

AFFIRMATIVE DEFENSES

94. DRL alleges and asserts the following affirmative defenses in response to the allegations in AstraZeneca's First Amended Complaint:

First Affirmative Defense
(Non-infringement of Valid and Enforceable Claims)

95. The manufacture, use, offer for sale, sale or importation of the product described in DRL's ANDA 202461 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or

enforceable claim of the '907, '504, '872, '466, '070 or '085 patents (collectively "patents-in-suit").

Second Affirmative Defense
(Invalidity)

96. At least claims 1, 5, 9-17, 21-24, 28-29, 32-35, 37, 41-42, 45-48, and 50-55 of the '907 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

97. All claims of the '504 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

98. All claims of the '872 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

99. All claims of the '070 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

100. All claims of the '085 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

101. All claims of the '466 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

Third Affirmative Defense
(Non-Infringement)

102. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL's ANDA 202461 does not and would not infringe at least claims 2-4, 6-8, 18-20, 25-27, 30-31, 36, 38-40, 43-44, and 49 of the '907 patent.

103. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL's ANDA 202461 does not and would not infringe at least claims 4, 8 and 9 of the '504 patent.

104. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL's ANDA 202461 does not and would not infringe at least claims 3, 6, 9 and 12 of the '872 patent.

105. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL's ANDA 202461 does not and would not infringe any claim of the '466 patent.

106. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL's ANDA 202461 does not and would not infringe any claim of the '070 patent.

107. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL's ANDA 202461 does not and would not infringe any claim of the '085 patent.

Fourth Affirmative Defense
(Prosecution History Estoppel)

108. Claims of the patents in suit are so limited as not to cover the manufacture, use, offer for sale, sale or importation of the product described in DRL's ANDA 202461 due to the arguments, statements, representations and/or amendments made by Plaintiffs to the United States Patent and Trademark Office during the prosecution of the respective applications leading to issuance of each of the patents in suit.

Fifth Affirmative Defense

109. Each of Plaintiffs' allegations of infringement of each of the patents in suit under 271(a), (b), and/or (c) fails to state a claim upon which relief can be granted.

COUNTERCLAIMS

110. Defendants/Counterclaimants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") by their attorneys, for their counterclaims against AstraZeneca AB, AstraZeneca LP, and Pozen Inc., (collectively, "Counterclaim Defendants or "AstraZeneca") allege and aver the following to seek a declaratory judgment that U.S. Patent Nos.: 6,926,907, 5,714,504, 6,875,872, 7,745,466, 6,369,085, 7,411,070, and 5,900,424 (respectively, the "'907 patent," "'504 patent," the "'872 patent," the "'466 patent," the "'085 patent," the "'070 patent," and the "'424 patent") are invalid and/or not infringed by the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202461.

PARTIES

111. Counterclaim Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

112. Counterclaim Plaintiff Dr. Reddy's Laboratories, Inc. is a New Jersey corporation, with its principal place of business at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey.

113. Counterclaim Defendant AstraZeneca AB is a corporation existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden. (*See* DE 1, ¶2).

114. Counterclaim Defendant AstraZeneca LP is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. (*See* DE 1, ¶3).

115. Counterclaim Defendant KBI-E, Inc. is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware. (*See* DE 42, ¶4).

116. Counterclaim Defendant Pozen, Inc. is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina, 27517. (*See* DE 1, ¶4).

BACKGROUND

117. DRL brings, and is entitled by statute to maintain, this action for declaratory judgment of patent non-infringement and invalidity under, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5), which are parts of the Hatch-Waxman Act amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2006 (2003) ("MMA").

118. Upon information and belief, AstraZeneca is the holder of approved New Drug Application ("NDA") No. 022511, and markets Vimovo,® known generically as esomeprazole magnesium and delayed-release naproxen tablets, throughout the United States pursuant to NDA No. 022511.

119. Upon information and belief, AstraZeneca owns the '504, '872, '466, '085, '070 and '424 patents. Upon information and belief Pozen, Inc. owns the '907 patent. By virtue of patent information that AstraZeneca submitted to FDA in connection with NDA No. 022511, the

‘907, ‘504, ‘872, ‘466, ‘085, ‘070 and ‘424 patents are listed in FDA’s compilation of approved drugs and their respective patents entitled “Approved Drug Products With Therapeutic Equivalence Evaluations,” commonly referred to as the “Orange Book.”

120. As a consequence of such Orange Book listing, AstraZeneca has maintained and affirmatively represented to the world that the ‘907, ‘504, ‘872, ‘466, ‘085, ‘070 and ‘424 patents claim the approved drug Vimovo,® or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including DRL, that attempts to market a generic version of Vimovo® before expiration of any one or more of the ‘907, ‘504, ‘872, ‘466, ‘085, ‘070 and ‘424 patents.

121. DRL seeks to market a generic version of Vimovo® before expiration of the ‘907, ‘504, ‘872, ‘466, ‘085, ‘070 and ‘424 patents. Therefore, as required by the FFDCA, DRL has submitted an ANDA and certified to the FDA that its ANDA product will not infringe any claim of the ‘907, ‘504, ‘872, ‘466, ‘085, ‘070 and ‘424 patents and/or that those patents are invalid or unenforceable, and has further notified AstraZeneca and Pozen of the legal and factual basis for that certification. DRL’s submission of the so-called “Paragraph IV Certifications” for the ‘907, ‘504, ‘872, ‘466, ‘085, ‘070 and ‘424 patents constitutes an artificial act of patent infringement putting DRL at considerable risk of being sued by Astra both before and after DRL’s market entry

122. Unless DRL obtains a Court order finding the ‘907, ‘504, ‘872, ‘466, ‘085, ‘070 and ‘424 patents invalid, unenforceable and/or not infringed, DRL will be irreparably harmed by the inability to market its generic product. A declaratory judgment from this Court can alleviate this harm and allow DRL to obtain approval of its ANDA product and compete in the market for esomeprazole magnesium and delayed-release naproxen tablets free from such potential liability.

123. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between DRL and AstraZeneca regarding the validity, enforceability and infringement of the '907, '504, '872, '466, '085, '070 and '424 patents over which this Court can and should exercise jurisdiction and declare the rights of the parties.

124. DRL is entitled by law to bring and maintain this action for declaratory judgment of patent non-infringement, unenforceability and/or invalidity under the Declaratory Judgment Act and the MMA where, as here, Astra did not sue DRL within 45 days of receipt of DRL's notice of paragraph IV certification as to the '424 patent, and DRL provided Astra an Offer of Confidential Access to DRL's ANDA for its generic esomeprazole magnesium and delayed-release naproxen tablets product.

125. DRL is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of DRL's proposed generic esomeprazole magnesium and delayed-release naproxen tablet product described in DRL's ANDA 202461("DRL's Proposed Product") does not and will not infringe any valid or enforceable claim of the '907, '504, '872, '466, '085, '070 and '424 patents.

126. Absent the exercise of jurisdiction by this Court and such declaratory relief, DRL and the American public will be irreparably harmed by the substantial delay in the market entry and availability of lower-priced generic esomeprazole magnesium and delayed-release naproxen tablets.

JURISDICTION AND VENUE

127. DRL realleges and incorporates by reference each of the allegations of paragraphs 110-126.

128. A substantial, present, genuine and justiciable controversy exists between DRL and AstraZeneca with respect to each of the '907, '504, '872, '085, '070, '466 and '424 patents.

129. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. §§ 1 et seq.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA, 28 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

130. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 et seq.; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the '907, '504, '872, '085, '070, '466 and '424 patents; and under the MMA, 28 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

131. This Court can and should declare the rights and legal relations of the parties regarding the '907, '504, '872, '085, '070, '466 and '424 patents pursuant to, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the MMA, 28 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

132. This Court has personal jurisdiction over AstraZeneca, *inter alia*, because of AstraZeneca's continuous and systematic contacts with the State of New Jersey, including its conducting of substantial and regular business therein through the marketing and sales of its pharmaceutical products in New Jersey, and because AstraZeneca has availed itself of the jurisdiction of this Court by initiating litigation in this District. *See, e.g., ASTRAZENECA AB, et al. v. RANBAXY PHARMACEUTICALS, INC., et al.*, Civil Action No. 3:05-cv-05553-JAP-TJB (D.N.J.); *ASTRAZENECA AB, et al. v. DR. REDDY'S LABORATORIES, LTD., et al.*, Civil

Action No. 3:08-cv-00328-JAP-TJB (D.N.J.); *ASTRAZENECA AB, et al. v. TEVA PARENTERAL MEDICINES, INC., et al*., Civil Action No. 3:08-cv-02014-JAP-TJB (D.N.J.); *ASTRAZENECA AB, et al. v. IVAX CORPORATION, et al*., Civil Action No. 3:08-cv-04993-JAP-TJB (D.N.J.); *ASTRAZENECA AB, et al. v. SANDOZ, INC.*, Civil Action No. 3:09-cv-00199-JAP-TJB (D.N.J.); *ASTRAZENECA AB, et al. v. LUPIN LTD., et al.*, Civil Action No. 3:09-cv-05404-JAP-TJB (D.N.J.); *ASTRAZENECA AB, et al. v. SUN PHARMA GLOBAL FZE, et al*., Civil Action No. 3:10-cv-01017-JAP-TJB (D.N.J.); *ASTRAZENECA AB, et al. v. HANMI USA, INC., et al*., Civil Action No. 3:11-cv-00760-JAP-TJB (D.N.J.); *ASTRAZENECA AB, et al. v. LUPIN LTD., et al.*, Civil Action No. 3:11-cv-04275-JAP-DEA (D.N.J.); and *ASTRAZENECA AB, et al.* v. ANCHEN PHARMACEUTICALS, INC. and ANCHEN, INC., Civil Action No. 3:11-cv-06348-JAP-DEA (D.N.J.).

133. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and/or 1400(b).

THE PATENTS-IN-SUIT

134. The '907 patent, entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," issued on August 9, 2005 and lists John R. Plachetka as an inventor. The '907 patent is currently listed in the Orange Book for VIMOVO.®

135. On information and belief, Pozen Inc. is the current owner by assignment of the '907 patent.

136. The '504 patent, entitled "Compositions," issued on February 3, 1998 and lists Per Lennart Lindberg and Sverker Von Unge as inventors. The '504 patent is currently listed in the Orange Book for VIMOVO.®

137. On information and belief, Astra Aktienbolag is the current owner by assignment of the '504 patent.

138. The '872 patent, entitled "Compounds," issued on April 5, 2005 and lists Per Lennart Lindberg and Sverker Von Unge as inventors. The '872 patent is currently listed in the Orange Book for VIMOVO.®

139. On information and belief, AstraZeneca is the current owner by assignment of the '872 patent.

140. The '466 patent, entitled "FORM OF S-OMEPRAZOLE," issued on Jun. 29, 2010 and lists Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller as inventors. The '466 patent is currently listed in the Orange Book for VIMOVO.®

141. On information and belief, AstraZeneca AB is the current owner by assignment of the '466 patent.

142. The '070 patent, entitled "FORM OF S-OMEPRAZOLE," issued on Aug. 12, 2008 and lists Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller as inventors. The '070 patent is currently listed in the Orange Book for VIMOVO.®

143. On information and belief, AstraZeneca AB is the current owner by assignment of the '070 patent.

144. The '085 patent, entitled "FORM OF S-OMEPRAZOLE," issued on April 9, 2002 and lists Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller as inventors. The '085 patent is currently listed in the Orange Book for VIMOVO.®

145. On information and belief, AstraZeneca AB is the current owner by assignment of the '085 patent.

146. The '424 patent, entitled "OMEPRAZOLE MAGNESIUM SALT FORM," issued on May 4, 1999 and lists Lars Åke Källström and Monica Annelie Nygren as inventors. The '424 patent is currently listed in the Orange Book for VIMOVO.®

147. On information and belief, Astra Aktiebolag is the current owner by assignment of the '424 patent.

The Actual Controversy Concerning the Orange Book Patents Listed For Vimovo®

148. An actual and justiciable controversy exists regarding the patents AstraZeneca asserted in its First Amended Complaint. Thus, an actual controversy exists between AstraZeneca and DRL as to whether there is any valid claim of the asserted '907, '504, '872, '466, '085 and '070 patents that has been or could be infringed by the manufacture, use and/or sale of either DRL's Proposed Product or an active pharmaceutical ingredient of the DRL's Proposed Product supplied by DRL to a third party or whether or not DRL's Proposed Product infringes certain claims of the '907, '504, '872, '466, '085 and/or '070 patents. DRL requires an immediate declaration of its rights vis-à-vis AstraZeneca with respect to the asserted patents.

149. On October 28, 2011, Counterclaim-Defendants filed the present Amended Complaint in this Court against DRL alleging patent infringement of the '907, '504, '872, '466, '085 and the '070 patents only by DRL's filing of ANDA No. 202461 for a generic version of VIMOVO.® Counterclaim-Defendants did not bring a lawsuit alleging infringement of the '424 patent by DRL's filing of ANDA No. 202461 for a generic version of VIMOVO.® But by listing the '424 patent in the Orange Book in connection with NDA No. 022511 for VIMOVO,® AstraZeneca maintains that the claims of this patent describe and cover VIMOVO,® or a method of using VIMOVO,® and that a suit for infringement could reasonably be brought against any ANDA applicant that attempts to seek approval to market a generic version of VIMOVO® before

the '424 patent expires. *See* 21 U.S.C. § 355(b)(1)-(c)(2). AstraZeneca's listing of the '424 patent in the Orange Book in connection with NDA No. 022511 creates the requisite justiciable case or controversy and subject matter jurisdiction for a generic manufacturer that makes a paragraph IV certification on these patents to bring a declaratory judgment action.

150. A generic manufacturer, like DRL, that has submitted an ANDA containing a paragraph IV certification on a patent is entitled to bring and maintain a declaratory judgment action against the NDA holder/patent holder on that patent if the following have occurred: (1) 45 days have elapsed since the paragraph IV certification was received by the NDA holder/patent holder; (2) neither the NDA holder nor the patent holder has filed a suit for patent infringement on the patent subject to the paragraph IV certification within the 45-day period; and (3) an offer of confidential access to the ANDA is included in the notice of paragraph IV certification provided to the NDA holder/patent holder. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

151. Because DRL has provided the offer to confidential access to its ANDA pursuant to 21 U.S.C. § 355(i)(5)(C)(i)(III) in its notice of paragraph IV certification dated September 19, 2011, and Counterclaim-Defendants did not sue DRL for infringement of the '424 patent within 45 days of receiving DRL's notice of paragraph IV certification, DRL is statutorily permitted to bring and maintain a declaratory judgment action against Counterclaim-Defendants pursuant to 21 U.S.C. § 355(j)(5)(C).

152. DRL further requires a court decision of non-infringement and/or invalidity on the '424 patent to prevent it from risking infringement liability on this patent if (and when) it begins marketing its generic version of VIMOVO® before this patent expires. This harm can be alleviated through a declaration of patent certainty on non-infringement and/or invalidity from this Court on the '424 patent.

First Counterclaim
Declaratory Judgment of Non-infringement ('907 Patent)

153. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

154. This counterclaim is for a declaration that the product described in DRL's ANDA 202461 does not infringe at least claims 2-4, 6-8, 18-20, 25-27, 30-31, 36, 38-40, 43-44, and 49 of the '907 patent.

Second Counterclaim
Declaratory Judgment of Invalidity ('907 Patent)

155. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

156. This counterclaim is for a declaration that at least claims 1, 5, 9-17, 21-24, 28-29, 32-35, 37, 41-42, 45-48, and 50-55 of the '907 patent are invalid under Title 35 United States Code, including *inter alia* §§101, 102, 103, 112, and for double patenting.

Third Counterclaim
Declaratory Judgment of Non-infringement ('504 Patent)

157. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

158. This counterclaim is for a declaration that the product described in DRL's ANDA 202461 does not infringe at least claims 4, 8 and 9 of the '504 patent.

Forth Counterclaim
Declaratory Judgment of Invalidity ('504 Patent)

159. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

160. This counterclaim is for a declaration that all claims of the '504 patent are invalid under Title 35 United States Code, including *inter alia* §§101, 102, 103, 112, and for double patenting.

Fifth Counterclaim
Declaratory Judgment of Non-infringement ('872 Patent)

161. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

162. This counterclaim is for a declaration that the product described in DRL's ANDA 202461 does not infringe at least claims 3, 6, 9 and 12 of the '872 patent.

Sixth Counterclaim
Declaratory Judgment of Invalidity ('872 Patent)

163. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

164. This counterclaim is for a declaration that all claims of the '872 patent are invalid under Title 35 United States Code, including *inter alia* §§101, 102, 103, 112, and for double patenting.

Seventh Counterclaim
Declaratory Judgment of Non-infringement ('466 Patent)

165. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

166. This counterclaim is for a declaration that the product described in DRL's ANDA 202461 does not infringe any claim of the '466 patent.

Eighth Counterclaim
Declaratory Judgment of Invalidity ('466 Patent)

167. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

168. This counterclaim is for a declaration that all claims of the '466 patent are invalid under Title 35 United States Code, including *inter alia* §§101, 102, 103, 112, and for double patenting.

Nineth Counterclaim
Declaratory Judgment of Non-infringement ('085 Patent)

169. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

170. This counterclaim is for a declaration that the product described in DRL's ANDA 202561 does not infringe any claim of the '085 patent.

Tenth Counterclaim
Declaratory Judgment of Invalidity ('085 Patent)

171. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

172. This counterclaim is for a declaration that all claims of the '085 patent are invalid under Title 35 United States Code, including *inter alia* §§101, 102, 103, 112, and for double patenting.

Eleventh Counterclaim
Declaratory Judgment of Non-infringement ('070 Patent)

173. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

174. This counterclaim is for a declaration that the product described in DRL's ANDA 202461 does not infringe any claim of the '070 patent.

Twelth Counterclaim
Declaratory Judgment of Invalidity ('070 Patent)

175. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

176. This counterclaim is for a declaration that all claims of the '070 patent are invalid under Title 35 United States Code, including *inter alia* §§101, 102, 103, 112, and for double patenting.

Thirteneenth Counterclaim
Declaratory Judgment of Non-Infringement ('424 Patent)

177. DRL repeats and realleges the allegations contained in paragraphs 110-152 as if fully set forth here.

178. This counterclaim is for a declaration that the product described in DRL's ANDA 202461 does not infringe any claim of the '424 patent.

PRAYER FOR RELIEF

WHEREFORE, DRL prays for relief as follows:

(a) That the First Amended Complaint against DRL be dismissed in its entirety and with prejudice and that the Plaintiffs take nothing thereby;

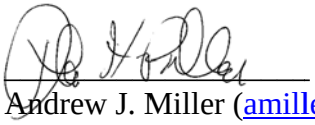
(b) That the Court permanently enjoin Plaintiffs from asserting any one or more of the '907, '504, '872, '466, '085, '070 and/or '424 patents against DRL or the purchasers of its Proposed Product;

(c) That this case be deemed to be an exceptional case within the meaning of 35 U.S.C. § 285;

(d) That DRL be awarded its attorney fees and costs and expenses of the suit, and;

(e) That the Court award other and further relief as it deems just and proper.

Dated: November 14, 2011

By: 

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CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2011, I caused a true and correct copy of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.'s Answer and Counterclaims to the First Amended Complaint to be served via e-mail and ECF upon:

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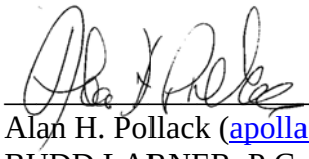

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